IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.
	)	
TARO PHARMACEUTICALS USA, INC. and TARO PHARMACEUTICAL INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendants Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively "Taro") alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave NW, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including FANAPT® (iloperidone oral tablets), for the treatment of schizophrenia.

2. On information and belief, Defendant Taro Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

3. On information and belief, Defendant Taro Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

4. On information and belief Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the State of Delaware and the United States.

5. On information and belief, Taro is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of Delaware and throughout the United States.

II. NATURE OF THE ACTION

6. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, *et seq*.) based upon Taro's infringement of one or more claims of Vanda's U.S. Patent No. 8,586,610 ("the '610 patent") and Taro's infringement of claim 1 of Vanda's U.S. Patent No. 9,138,432 ("the '432 patent"), which relate to the field of schizophrenia treatment.

7. On information and belief, Taro Pharmaceuticals USA, Inc., by and with Taro Pharmaceutical Industries, Ltd., filed an Abbreviated New Drug Application No. 207098 (the "Taro ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic iloperidone tablets in their 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia.

8. Taro has infringed one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Taro ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic iloperidone for the treatment of schizophrenia prior to the expiration of the '610 patent, or any extensions thereof. Taro will infringe one or more claims of the '610 patent under 35 U.S.C.

§ 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia prior to the expiration of the '610 patents, or any extensions thereof.

9. Taro has infringed claim 1 of the '432 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Taro ANDA, including its filing of any amendments or supplements thereto, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic iloperidone for the treatment of schizophrenia prior to the expiration of the '432 patent, or any extensions thereof. Taro will infringe claim 1 of the '432 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia according to the methods of the '432 patent prior to the expiration of that patent, or any extensions thereof.

III. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Taro by virtue of the fact that, *inter alia*, both Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. have committed, induced, contributed to, aided, abetted, or participated in in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Vanda, a Delaware corporation. This Court has personal jurisdiction over Taro for the additional reasons set forth below.

12. This Court has personal jurisdiction over Taro, by virtue of, *inter alia*, its activities (*e.g.*, filing the Taro ANDA seeking approval to market generic iloperidone prior to the

expiration of the ’610 and ’432 patents along with a Paragraph IV certification regarding its intent to market generic iloperidone and sending notice of that Paragraph IV certification), which were purposefully directed to the State of Delaware, where Vanda is organized. As a result, the consequences of Taro’s actions were (and will be) suffered in Delaware. Taro knew or should have known that Vanda is a Delaware corporation and thus Taro knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

13. This Court also has personal jurisdiction over Taro because at the time Taro sent notice of a Paragraph IV certification, it was reasonably foreseeable that Taro would be sued within 45 days in this District, where Vanda is organized and where related ANDA litigation over generic iloperidone, including litigation based on infringement of the ’610 patent, had already been filed (C.A. Nos. 13-1973 (GMS), 14-757 (GMS) (consolidated); C.A. No. 15-362 (GMS)). Taro knew or should have known that Vanda is a Delaware corporation and Taro knew or should have known that there is related ANDA litigation over generic iloperidone, including litigation based on infringement of the ’610 patent, pending in Delaware.

14. This Court also has personal jurisdiction over Taro because this suit arises out of and relates to Taro’s activities that are, and will be, directed to Delaware. On information and belief, Taro develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and throughout the United States. Thus, on information and belief, Taro does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. These continuous and systematic contacts, including, but not limited, to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Taro.

15. This Court also has personal jurisdiction over Taro because, on information and belief, Taro has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Taro brought a patent infringement lawsuit in this district to protect two patents on July 28, 2014 (C.A. No. 14-989 (RGA)). Taro Pharmaceuticals USA, Inc. was listed as a Plaintiff, and Taro Pharmaceutical Industries, Ltd. states that it had filed the lawsuit in its most recent Securities and Exchange Commission Form 20-F, for the fiscal year ended March 31, 2015. Additionally, Taro Pharmaceuticals USA, Inc. brought another patent infringement lawsuit in this district on September 22, 2015 (C.A. No. 15-859 (RGA)).

16. On information and belief, Taro, following any FDA approval of the Taro ANDA, will sell the generic product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States.

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

IV. THE PATENTS-IN-SUIT – U.S. PATENT NOS. 8,586,610 AND 9,138,432

18. The allegations of ¶¶ 1-17 are incorporated herein by reference.

19. On May 6, 2009, FDA approved Vanda's new drug application 22-192 for FANAPT® (iloperidone oral tablets) in their 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of schizophrenia ("FANAPT® NDA").

20. Vanda is the owner of all rights, title and interest in the '610 patent, entitled "Methods for the Administration of Iloperidone." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '610 patent on November 19, 2013, to Curt D. Wolfgang and Mihael H. Polymeropoulos, which was assigned to Vanda. A true and correct copy of the '610 patent is attached to this Complaint as Exhibit A.

21. The ’610 patent covers methods of using FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia in certain patients based on whether the patients are poor metabolizers of FANAPT®. The patients that are poor metabolizers of FANAPT® have certain mutations of a gene known as CYP2D6. The ’610 patent covers the identification of patients that are poor metabolizers by genotyping and making a specific dose reduction—the dosage must be halved—in those patients to avoid prolonged QTc as measured by an electrocardiogram (“EKG”). Various studies have shown that patients with QTc prolongation may have an increased risk of cardiovascular side effects, including serious arrhythmias, such as ventricular tachycardia, ventricular fibrillation, and irregular heartbeats (torsades de pointes or TDP), which could lead to cardiac death.

22. The prescribing information for FANAPT® (“FANAPT® Label”), instructs physicians to (1) determine whether the patient is a poor CYP2D6 metabolizer using available laboratory tests,[1] and (2) administer either the target dose if the patient is a normal CYP2D6 metabolizer or a halved dosage if the patient is a poor CYP2D6 metabolizer.

23. On information and belief, the Taro ANDA essentially copies the FANAPT® Label as required by FDA, see 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to administer either the target dose if the patient is a normal CYP2D6 metabolizer or a halved dosage if the patient is a poor CYP2D6 metabolizer.

24. Thus, the use of FANAPT® (iloperidone oral tablets) and any generic iloperidone for the treatment of schizophrenia is covered by the ’610 patent, and Vanda has the right to enforce the ’610 patent.

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[1] There are numerous commercially available genotyping assays (offered by Laboratory Corporation of America, Roche Molecular Systems, Illumina, Quest Diagnostics, AutoGenomics, etc.).

25. FDA listed the '610 patent in the Orange Book for FANAPT® in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths on January 15, 2015.

26. Vanda is the owner of all rights, title and interest in the '432 patent, entitled "Methods for the Administration of Iloperidone." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '432 patent on September 22, 2015, to Curt D. Wolfgang and Mihael H. Polymeropoulos, which was assigned to Vanda. A true and correct copy of the '432 patent is attached to this Complaint as Exhibit B.

27. The '432 patent claims "[a] method of decreasing a risk of QT prolongation in a patient being treated for schizophrenia with iloperidone, the method comprising: administering to the patient a dose of iloperidone that is 24 mg/day if, and because, the patient is not being treated with fluoxetine; and administering to the patient a dose of iloperidone that is 12 mg/day if, and because, the patient is being treated with fluoxetine."

28. The FANAPT® Label instructs physicians that "The maximum recommended dose is 12 mg twice daily (24 mg/day)" and that "FANAPT dose should be reduced by one-half [*i.e.*, the dose should be reduced to 6 mg twice daily (12 mg/day)] when administered concomitantly with strong CYP2D6 inhibitors such as fluoxetine or paroxetine."

29. On information and belief, the Taro ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to administer either the maximum recommended dose of 24 mg/day if the patient is not being treated with fluoxetine or a halved dosage of 12 mg/day if the patient is being treated with fluoxetine.

30. Thus, the use of FANAPT® (iloperidone oral tablets) and any generic iloperidone for the treatment of schizophrenia is covered by the '432 patent, and Vanda has the right to enforce the '432 patent.

31. FDA listed the '432 patent in the Orange Book for FANAPT® in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths on September 23, 2015.

COUNT I
(INFRINGEMENT OF THE '610 PATENT)

32. The allegations of ¶¶ 1-31 are incorporated herein by reference.

33. On information and belief, Taro filed the Taro ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic iloperidone for the treatment of schizophrenia before the expiration of the '610 patent, and any extensions thereof.

34. On or about September 4, 2015, Vanda received a letter ("Taro Notice Letter") dated September 3, 2015, stating that Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. had filed the Taro ANDA seeking approval to manufacture, use, offer to sell, and sell generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia. On information and belief, Taro seeks to do so before the expiration of the '610 patent or any extensions thereof.

35. On information and belief, the Taro ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to (1) determine whether the patient is a poor CYP2D6 metabolizer using available laboratory tests, and (2) administer either the target dose if the patient is a normal CYP2D6 metabolizer or a halved dosage if the patient is a poor CYP2D6 metabolizer.

36. Taro has infringed the ’610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Taro ANDA to FDA for generic iloperidone tablets in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths, for the treatment of schizophrenia, which are covered by one or more claims of the ’610 patent.

37. Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. are jointly and severally liable for the infringement of one or more claims of the ’610 patent. Taro’s participation in, contribution to, inducement of, aiding or abetting the submission of the Taro ANDA to FDA constitutes direct, contributory, or induced infringement of one or more claims of the ’610 patent under 35 U.S.C. § 271(e)(2)(A).

38. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Taro ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the ’610 patent.

39. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Taro ANDA be a date that is not earlier than the expiration of the ’610 patent, or any later expiration of exclusivity for the ’610 patent to which Vanda becomes entitled.

40. Vanda will be irreparably harmed if Taro is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the ’610 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

41. On information and belief, Taro’s statement of the factual and legal basis for its opinion regarding the validity of the ’610 patent is devoid of an objective good faith basis

in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

42. To the extent Taro commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

COUNT II
(INFRINGEMENT OF THE '432 PATENT)

43. The allegations of ¶¶ 1-42 are incorporated herein by reference.

44. On information and belief, Taro filed the Taro ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic iloperidone for the treatment of schizophrenia before the expiration of the '432 patent, and any extensions thereof.

45. On or about September 4, 2015, Vanda received the Taro Notice Letter dated September 3, 2015, stating that Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. had filed the Taro ANDA seeking approval to manufacture, use, offer to sell, and sell generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia. On information and belief, Taro seeks to do so before the expiration of the '432 patent, or any extensions thereof.

46. On information and belief, the Taro ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to administer either the maximum recommended dose of 24 mg/day if the patient is not being treated with fluoxetine or a halved dosage of 12 mg/day if the patient is being treated with fluoxetine.

47. Taro infringes the '432 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Taro ANDA, including any amendments or supplements thereto, to FDA

for generic iloperidone in their 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia, which are covered by claim 1 of the ’432 patent.

48. Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. are jointly and severally liable for the infringement of claim 1 of the ’432 patent. Taro’s participation in, contribution to, inducement of, aiding or abetting the submission of the Taro ANDA to FDA constitutes direct, contributory, or induced infringement of claim 1 of the ’432 patent under 35 U.S.C. § 271(e)(2)(A).

49. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Taro ANDA be a date that is not earlier than the expiration of the ’432 patent, or any later expiration of exclusivity for the ’432 patent to which Vanda becomes entitled.

50. Vanda will be irreparably harmed if Taro is not enjoined from infringing or actively inducing or contributing to infringement of claim 1 of the ’432 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

51. To the extent Taro commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

COUNT III
(DECLARATORY JUDGMENT OF INFRINGMENT OF THE ’432 PATENT)

52. The allegations of ¶¶ 1-51 are incorporated herein by reference.

53. Upon information and belief, Taro intends to, and will manufacture, use, offer to sell, or sell within the United States, or import into the United States, generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths immediately and imminently upon FDA approval of the Taro ANDA.

54. If Taro manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, generic iloperidone in its 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths prior to the expiration of the ’432 Patent for the methods of use claimed in that patent, Taro will infringe claim 1 of the ’432 Patent under 35 U.S.C. § 271 (a), (b), and/or (c).

55. An actual controversy has arisen and now exists between the parties concerning whether Taro’s generic iloperidone will infringe claim 1 of the’432 Patent.

56. An actual controversy has also arisen and now exists between the parties concerning whether Taro’s filing of the Taro ANDA will infringe 35 U.S.C. § 271(e)(2)(A) if Taro amends the Taro ANDA after the ’432 Patent issued and was timely listed in the Orange Book and/or if Taro issues a Paragraph IV certification regarding the ’432 Patent.

57. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., the Court has the power to, and should, declare the rights of the parties regarding any infringement by Taro of the ’432 Patent.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Taro and grant the following relief:

A. an adjudication that Taro has infringed directly, contributed to, or induced the infringement of one or more claims of the ’610 patent under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA the Taro ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia before the expiration of the ’610 patent;

B. a judgment that Taro infringes claim 1 of the ’432 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Taro ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia, including any amendments or supplements thereto, before the expiration of the ’432 patent;

C. a judgment declaring that Taro will infringe directly, contribute to, or induce the infringement of claim 1 of the ’432 patent under 35 U.S.C. § 271(e)(2)(A) if Taro amends the Taro ANDA after the ’432 Patent issued and was timely listed in the Orange Book or issues a Paragraph IV certification directed at that patent;

D. a judgment declaring that the commercial manufacture, use, offer for sale, sale, or importation of the products described in the Taro ANDA would constitute infringement of claim 1 of the ’432 patent, or inducement of or contribution to such conduct, by Taro pursuant to 35 U.S.C. § 271 (a), (b), or (c);

E. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Taro ANDA for generic iloperidone be a date that is not earlier than the date of the expiration of the ’610 patent or any later period of exclusivity to which Vanda is or may become entitled;

F. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Taro ANDA for generic iloperidone be a date that is not earlier than the date of the expiration of the ’432 patent or any later period of exclusivity to which Vanda is or may become entitled;

G. a permanent injunction enjoining Taro, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or

participation with any of them from infringing the ’610 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Taro ANDA;

H. a permanent injunction enjoining Taro, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’432 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Taro ANDA;

I. an order enjoining Taro, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’610 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Taro ANDA while the litigation is pending;

J. an order enjoining Taro, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’432 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Taro ANDA while the litigation is pending;

K. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Taro ANDA would constitute

infringement of one or more claims of the '610 patent, or inducement of or contribution to such conduct, by Taro pursuant to 35 U.S.C. § 271 (a), (b), or (c);

L. an assessment of pre-judgment and post-judgment interest and costs against Taro, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

M. an award to Vanda of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

N. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

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